

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/16/2015 9:48:28 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Imports, FYI...

thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:45 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: Imports, FYI...

Daniel Rosenberg's Blog

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

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Posted September 16, 2015

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The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue [to overstate](#) (see also [here](#)) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the [Safer Chemicals Healthy Families](#) coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one

key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use

in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet -- regarding the reasonable potential of exposure to the fibers from any article or category of

articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erionite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

Or consider EPA's recent significant new use rule for benzidine dyes, finalized last December. EPA identified the breakdown products of benzidine dyes as known human carcinogens, and referenced evidence of potential exposure from the dyes in clothes and textile-related uses. Based on the available information EPA had regarding the chemical's toxicity, and the potential for exposure from clothing, footwear and textiles, EPA imposed a new use notice requirement for any new use of benzidine dyes, and lifted the articles exemption, making the notice requirement applicable to potential new uses of benzidine dyes in articles (products) to be imported into the U.S.

Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the chemical -- for example, other categories of articles for which EPA did not already have some exposure information -- a court might rule that EPA did not have the authority to extend notice requirements to those uses, despite the agency's concerns about the chemicals' potential harm to health or the environment. Relying on the argument that EPA *might* prevail in such a lawsuit as an excuse for not flatly rejecting the proposed weakening of current law is simply irresponsible. The new Senate language in fact makes it more likely that articles containing chemicals of concern to EPA will be imported into the U.S. It is also directly contrary to what the drafters of the original TSCA intended.

In the Committee report filed when TSCA was originally passed in 1976, the Senate Commerce Committee (which handled TSCA then) noted the heightened concern about chemicals causing cancer, birth defects and other harms to health and the environment and the limited scope of other existing laws that touched in various ways on the problem of chemical pollution including the Clean Air Act, Clean Water Act, Occupational Safety and Health Act and the Consumer Product Safety Act: "None of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins. The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest....If hazards are to be discovered and prevented prior to the manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision... the pre-market notification provisions of the committee bill forms [sic] the backbone of the preventive aspects of health protection sought by this legislation."

EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
- Toluene Diisocyanates (TDI) and related compounds - that are dermal and inhalation sensitizers that can cause asthma and lung damage;
- Hexabromocyclododecane (HBCD) - a flame retardant ingredient linked to hormone disruption, aquatic toxicity and a possible reproductive toxin that is already subject to authorization (meaning likely phase out) under the

European Union's REACH regulation and a global phase-out under the Persistent Organic Pollutants (POPs) treaty;

- Polybrominated Diphenyl Ethers (PBDEs) - another group of flame retardants that are persistent, bioaccumulative and toxic.

In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- exactly what the agency should be doing under TSCA. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

Efforts to limit EPA's ability to obtain information about potential new uses of chemicals of concern in products before they reach the market, are swimming against the tide of chemical regulation around the world, as well as consumer satisfaction and acceptance. Public demand (and therefore retailer demand) to know what chemicals are used in products is not going away. Contrary to the hopes of many in industry who are salivating for passage of the Udall/Vitter bill, flawed TSCA reform legislation will not stem that tide. EPA's existing authority to obtain information about potential new uses of chemicals of concern before they are imported into the U.S. in products is a modest and effective method of ensuring some degree of protection for the public. Constraining EPA's authority to target articles for significant new use notification is the industry's over-reaction to EPA's exercising its authority in a handful of instances. But increasing the burden on EPA and limiting its ability to take these steps will be met with its own reaction - more action at the state level, and in the marketplace - something these same industries should seriously contemplate before taking a step that could easily backfire.

Members of Congress who consider themselves supporters and protectors of EPA's role in protecting public health and the environment should carefully consider (or reconsider) their support for legislation containing this very problematic provision. If the Senate does not have the fortitude to tell these companies that this special interest provision to weaken current TSCA is an early Christmas gift that they cannot have, then the White House should make clear that it needs to come out of the bill before TSCA reform legislation reaches the President's desk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/3/2015 9:17:23 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Animal Testing

Michal,

Although there were no EPA TA comments on the animal testing provisions of the latest version of the Senate bill, on earlier versions of the bill EPA pointed out inconsistent use of "vertebrate animal" and "animal". This inconsistency remains, please see our TA below.

- The animal testing provisions of section 4(c) remain inconsistent as to whether the goal is reduce animal testing or only vertebrate animal testing. For example, the overall goal seems to be to minimize use of vertebrate animals (sec 4(c)(1)), but in service of that goal EPA must encourage and facilitate use of test methods that eliminate or reduce the use of animals (sec 4(c)(1)(A)(iii)).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, December 01, 2015 2:42 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on House CBI

Thanks very much. On animal testing – just confirming that EPA has no drafting issues or concerns w implementing the as-reported provisions in S 697 beyond what you sent me?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, December 01, 2015 2:40 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on House CBI

Michal,

This follows up on your technical assistance request on the CBI provisions of the House TSCA bill. We have two TA comments on the attached version of the House bill.

- page 20 lines 14-17: this new text (amending section 14(b)(1)) would protect the confidentiality of chemical formulas, including molecular structures, in health and safety studies, which would result in the protection of specific chemical IDs. This would significantly curtail the release of chemical IDs in health and safety studies, which are releasable under current section 14 unless they reveal process information.

- page 22, lines 12-13: Section 14(c)(1)(C) requires EPA to provide notice to the submitter of impending release of information claimed as CBI, unless "a request for renewal is granted under subparagraph (B)." But subparagraph (B) does not require EPA to grant a renewal request; it merely requires that a request be submitted

I think this completes the outstanding TA requests, please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
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Washington, DC 20460
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From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: November 27, 2015 at 7:10:48 AM EST

To: Nichole DiStefano <DiStefano.Nichole@epa.gov>

Subject: TA (good to start on this Monday)

Hi Nichole and hope you had a good holiday

While I am thinking about itn, I wanted to request EPA TA on the following provisions:

- animal testing in Senate bill
- CBI provisions in both House and Senate bill

Guessing and hoping you've already done this for others and it will just be a matter of digging it out. Either way, it can definitely wait til Monday.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/1/2015 6:19:30 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on several issues

Michal,
Thanks for the additional information. Would 5pm work for you in case I can get folks together tonight. Best,
Sven

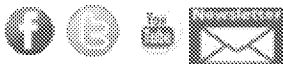
Sven-Erik Kaiser
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Washington, DC 20460
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, July 01, 2015 2:12 PM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey)
Subject: RE: TSCA call time?

- The nexus between waste storage and TSCA
- Cost-benefit analysis for bans/phase-outs (as contemplated in S 697)
- The nexus between information that has led EPA to put a chemical on its TSCA workplan, information that other countries develop as part of their rulemakings, information that would be used by IARC and NAS, and information that EPA is likely to request from companies as part of either prioritization or the safety assessment/determination phase (this sounds like a more complicated question than I think it is)
- Implementation dates vs effective dates

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
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202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, July 01, 2015 1:55 PM
To: Freedhoff, Michal (Markey)
Cc: Joseph, Avenel (Markey)
Subject: Re: TSCA call time?

Checking- can you give me an idea of what's on your list. Thanks,
Sven

On Jul 1, 2015, at 1:51 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Hi Sven

I know it is short notice during a holiday week, but is there any chance that some or all of team TSCA could talk this afternoon or tomorrow morning? I have a few questions that I need some help with following a meeting. I think they'd be relatively easily answered by phone.

Thanks

Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/1/2015 5:55:14 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Re: TSCA call time?

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Sven

On Jul 1, 2015, at 1:51 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/29/2015 6:04:41 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkle.senate.gov]
Subject: SEPW TSCA TA

Jonathan,

I think there are 3 outstanding TA requests below. The first two are underway and included is the response to the small manufacturers definition question. Please let me know if any additional questions. Thanks,
Sven

- exports (EPA working on TA)
- cap on industry assessments (EPA to provide text change on p.22, line 18)
- small manufacturers definition

EPA response: most of EPA's TSCA programs, including CDR, use the same definition for small business as defined by regulation in 40 CFR 704.3. This definition has never been updated. A few TSCA programs use different definitions of small business, including for 8(a) PAIR and for calculating PMN fees.

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

(1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

(3) *Inflation index.* EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide Federal Register notification when changing the total annual sales values.

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From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 29, 2015 1:37 PM

To: Kaiser, Sven-Erik

Cc: Karakitsos, Dimitri (EPW); Zipkin, Adam (Booker); Deveny, Adrian (Merkley)

Subject: Follow-up

Hey Sven, sorry again to miss the call last week. My understanding was there might be one more follow-up on exports? Are we waiting for anything from EPA?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/26/2015 2:14:15 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: House TSCA bill

Jerry,

Thanks. We're seeing a slightly earlier version on congress.gov and want to make sure we're using the right one. Best,
Sven

On Jun 24, 2015, at 3:27 PM, "Couri, Jerry" <JerryCouri@mail.house.gov> wrote:

<sus_01_xml (3).pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/30/2015 3:41:33 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Requests

Thanks

On Nov 30, 2015, at 10:34 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Nothing specific – on animal testing and CBI, past TA is totally fine, but what I have seen on CBI in the past TA has been on a Senate version that is very different from the current version. I also haven't seen anything by way of TA on the House CBI provision. I don't want you to spend a ton of time developing new material.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]
Sent: Monday, November 30, 2015 10:09 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Requests

Michal – we're getting together this morning to review the TSCA TA requests. On the new animal testing and CBI questions – is there anything specific? If not, we can review past TA, some that you already have in the comprehensive Senate bill TA, and put something together. Please let me know if any requests are more urgent than others to help with prioritizing. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/30/2015 3:09:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Requests

Michal – we're getting together this morning to review the TSCA TA requests. On the new animal testing and CBI questions – is there anything specific? If not, we can review past TA, some that you already have in the comprehensive Senate bill TA, and put something together. Please let me know if any requests are more urgent than others to help with prioritizing. Thanks,
Sven

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U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/25/2015 4:52:54 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on Preemption

Understood. Are you going to send any additional requests following the call? Thanks,
Sven

On Nov 25, 2015, at 11:42 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, meaning I don't need anything written on this....

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Freedhoff, Michal (Markey)
Sent: Wednesday, November 25, 2015 11:42 AM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey TSCA TA request on Preemption

We covered this. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]
Sent: Wednesday, November 25, 2015 8:26 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on Preemption

Michal, got it. Thanks,

Sven

On Nov 25, 2015, at 7:21 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

In both the House and Senate TSCA bills (and in underlying TSCA) there is some degree of section 5 preemption, w Senate bill being the least preemptive and House bill being the most.

I'd like to understand, as a legal matter, what happens to a new chemical once it is no longer a new chemical and goes on the inventory because it is being manufactured.

In EPA's views, do the effects of section 5 preemption disappear when the chemical becomes an "existing chemical" such that if, 20 years after it goes on the market and risks about it become more known, a state could regulate it subject to whatever section 6 preemption exists?

If the response to that question is different for any of House, Senate or underlying TSCA, I'd also appreciate an explanation as to where in the text those differences arise.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/24/2015 7:22:00 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HR 2576

Jerry – we're having some uncertainty about whether we have the version of the bill that passed the House. Different websites seem to have different versions. At your convenience, can you send me the final version?
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/24/2015 2:16:36 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: thanks for your help with tsca

Jerry,
Congratulations to you and Dave and your whole team. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Wednesday, June 24, 2015 9:46 AM
To: Kaiser, Sven-Erik
Subject: thanks for your help with tsca

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/23/2015 5:01:02 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: SEPW TSCA TA on testing agreements, exports, SBA

Jonathan,
The call went well. Some follow up items for EPA on the SBA issue, the industry requested assessment cap, and exports. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, June 23, 2015 12:27 PM
To: Kaiser, Sven-Erik
Subject: RE: 1 item: S.697

Call go ok? sorry I had to miss. Had to talk to my boss about the NYT article.

-----Original Message-----

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, June 23, 2015 11:55 AM
To: Black, Jonathan (Tom Udall); Jones, Jim
Subject: RE: 1 item: S.697

Thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, June 23, 2015 11:13 AM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: RE: 1 item: S.697

Report attached

-----Original Message-----

From: Black, Jonathan (Tom Udall)
Sent: Friday, June 19, 2015 8:38 AM
To: 'Jones.Jim@epa.gov'; 'Kaiser.Sven-Erik@epamail.epa.gov'
Subject: Fw: 1 item: S.697

----- Original Message -----

From: LIS ALERT [mailto:lisalert@loc.gov]
Sent: Friday, June 19, 2015 08:10 AM
To: Black, Jonathan (Tom Udall)
Subject: 1 item: S.697

1 item (1 changed) in Bill Summary & Status

Bill(s) with changes in the parameters you selected:

1. S.697 - A bill to amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Sponsor: Sen Udall, Tom [D-NM] (introduced 3/10/2015)
Bill Status: 6/18/2015: By Senator Inhofe from Committee
on Environment and Public Works filed written report.
Report No. 114-67. Minority views filed.
<http://www.lis.gov/cgi-lis/bdquery/z?d114:SN00697:/>

This email contains the results of a search run daily, Mon-Fri.

VIEW your latest alert results via the web, <http://www.lis.gov/cgi-lis/casms?op=b&sDt=today>

MODIFY or delete this LIS Email Alert from My Searches & Alerts, <http://www.lis.gov/cgi-lis/casms?&op=1>

EMAIL questions and comments to lismail@crs.loc.gov <http://www.lis.gov/homepage/feedback.html>

Please do not reply to this message.

This is a service of LIS, <http://www.lis.gov>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/23/2015 3:54:48 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: RE: 1 item: S.697

Thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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To: Jones, Jim; Kaiser, Sven-Erik
Subject: RE: 1 item: S.697

Report attached

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Subject: Fw: 1 item: S.697

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Sponsor: Sen Udall, Tom [D-NM] (introduced 3/10/2015)
Bill Status: 6/18/2015: By Senator Inhofe from Committee on Environment and Public Works filed written report.
Report No. 114-67. Minority views filed.
<http://www.lis.gov/cgi-lis/bdquery/z?d114:SN00697:/>

This email contains the results of a search run daily, Mon-Fri.
VIEW your latest alert results via the web, <http://www.lis.gov/cgi-lis/casms?op=b&sDt=today>

MODIFY or delete this LIS Email Alert from My Searches & Alerts, <http://www.lis.gov/cgi-lis/casms?&op=1>

EMAIL questions and comments to lismail@crs.loc.gov <http://www.lis.gov/homepage/feedback.html>
Please do not reply to this message.

This is a service of LIS, <http://www.lis.gov>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/22/2015 9:29:58 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan,
We'll be prepared. Do you know what the angle is on the SBA question? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 4:57 PM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Thanks. we'll have the usual suspects on the call. give me a buzz if you want me to run through the list. Otherwise, talk to you tomorrow. Thanks!

Ex. 6 - Personal Privacy

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 4:52 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Cc: Zipkin, Adam (Booker)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Got it – will pass along. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 4:51 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Cc: Zipkin, Adam (Booker)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Hi! Another topic that may also come up tomorrow: we would also like to discuss the existing TSCA Section 8(a)(3)(B) requirement that the Administrator consult with the SBA Administrator to propose standards for determining which manufacturers and processors qualify as small manufacturers and processors

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]
Sent: Monday, June 22, 2015 1:48 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Great – for the call on Tues, June 23 at 10 am, please call **Ex. 6 - Personal Privacy** Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 1:47 PM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Can we do tomorrow at 10am? Do you have a number we can call into?

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]
Sent: Monday, June 22, 2015 1:24 PM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri,
Availability for a call on testing:
- Tues, June 23 from 10-12
- Weds, June 24 at 1

Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 11:56 AM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Sorry, yes, I meant this week.

We could do this on the phone.

We're nearing completion on the full package, too, and will probably want to sit with you as to walk through them all. not sure if we will be able to do that this week or next week.

What is your availability tomorrow to discuss consent agreements?

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Sent: Monday, June 22, 2015 11:54 AM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri – we'll be glad to talk about agreements for testing. We're you thinking this week (week of June 22) or next week (week of June 29). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
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Sent: Monday, June 22, 2015 11:48 AM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Sec 12 edits revised for TA 6-18-15

Sven,

Thank you for the recent TA you provided. We have a follow-up request on two of the issues.

1. Section 12, Exports. We agree with your points in the prior TA and have struck the references to sections 5 and 6 and to the safety standard. However, the intent all along has been to apply the exceptions both to new chemicals that are found likely to present an unreasonable risk in the U.S., and to existing chemicals that are found present or will present an unreasonable risk. Hence, the language below retains the two subparagraphs; see attachment. Subparagraph (A) uses the term "new chemical substance" which is defined in TSCA, while (B) refers more generally to chemical substances. Does this work?
2. We have a lot of questions regarding consent agreements for testing in relation to other provisions of the bill, including citizen civil actions. We would like to find a time to meet next week to discuss this issue with you. Would you be able to do so?

Thank you ...

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/22/2015 8:51:41 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

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Sven

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U.S. EPA
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Sven

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U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
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Can we do tomorrow at 10am? Do you have a number we can call into?

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Sent: Monday, June 22, 2015 1:24 PM

To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri,
Availability for a call on testing:
- Tues, June 23 from 10-12
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Thanks,
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Sven-Erik Kaiser
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Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Sec 12 edits revised for TA 6-18-15

Sven,

Thank you for the recent TA you provided. We have a follow-up request on two of the issues.

1. Section 12, Exports. We agree with your points in the prior TA and have struck the references to sections 5 and 6 and to the safety standard. However, the intent all along has been to apply the exceptions both to new chemicals that are found likely to present an unreasonable risk in the U.S., and to existing chemicals that are found present or will present an unreasonable risk. Hence, the language below retains the two subparagraphs; see attachment. Subparagraph (A) uses the term "new chemical substance" which is defined in TSCA, while (B) refers more generally to chemical substances. Does this work?
2. We have a lot of questions regarding consent agreements for testing in relation to other provisions of the bill, including citizen civil actions. We would like to find a time to meet next week to discuss this issue with you. Would you be able to do so?

Thank you ...

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/22/2015 5:24:16 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri,
Availability for a call on testing:
- Tues, June 23 from 10-12
- Weds, June 24 at 1

Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, June 22, 2015 11:56 AM
To: Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request on Agreements for Testing

Sorry, yes, I meant this week.

We could do this on the phone.

We're nearing completion on the full package, too, and will probably want to sit with you as to walk through them all. not sure if we will be able to do that this week or next week.

What is your availability tomorrow to discuss consent agreements?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, June 22, 2015 11:54 AM
To: Black, Jonathan (Tom Udall)
Cc: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA Request on Agreements for Testing

Jonathan and Dimitri – we'll be glad to talk about agreements for testing. We're you thinking this week (week of June 22) or next week (week of June 29). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [<mailto:Jonathan.Black@tomudall.senate.gov>]
Sent: Monday, June 22, 2015 11:48 AM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: Sec 12 edits revised for TA 6-18-15

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Sent: 6/22/2015 3:53:50 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: SEPW TSCA TA Request on Agreements for Testing

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Sent: 7/22/2015 1:13:17 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
Available today for a call 10-11:30 and after 3pm. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Tuesday, July 21, 2015 8:07 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Sven that would be great -- I would be interested to talk to any attorney that knows both. Please let me know when might be a good time. Adam

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 21, 2015 11:46 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
On further reflection here, if you want to discuss further about the relationship between TSCA and FIFRA, I can offer a call with one of our attorneys who handles both statutes (sort of like speaking two languages). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Monday, July 20, 2015 9:15 AM
To: 'Zipkin, Adam (Booker)'
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
FIFRA includes pests – defined as living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals. Examples include:

- insects,
- mice and other animals (this is where the coyotes come in)

- unwanted plants (weeds),
- fungi, and
- microorganisms such as bacteria and viruses.

Please let me know if you would like a call with FIFRA folks on sodium fluoroacetate. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Sunday, July 19, 2015 2:49 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Thanks Sven -- that is helpful, as I am still learning. Please see attached article which states "Sodium Fluoroacetate, also highly toxic, is a "restricted use" chemical, that is only approved for use to protect livestock from coyotes and can only be used by a licensed professional" -- so that approved use (protecting livestock from coyotes) is pursuant to FIFRA? When I think of pesticides, I tend to think of chemicals used to kill bugs, not coyotes -- but sounds like definition of "pest" may be broader than I thought and include animals such as coyotes?

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]
Sent: Friday, July 17, 2015 7:17 PM
To: Zipkin, Adam (Booker)
Subject: Sen. Booker TSCA TA Request on Compound 1080

Adam --

Sodium fluoroacetate is registered for use as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Like all chemicals with pesticidal uses, this chemical is currently outside of TSCA's jurisdiction to the extent that it is "manufactured, processed, or distributed in commerce for use as a pesticide." See the definition of "chemical substance" at TSCA Section 3(2)(B)(ii).

Please clarify whether you are inquiring about a TSCA ban of the non-pesticidal uses of sodium fluoroacetate, or about a TSCA ban of the pesticidal uses of sodium fluoroacetate. (The latter would require altering the TSCA definition of "chemical substance"). This clarification will help us to scope our response accordingly.

Thanks,

Sven

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Hello Sven. Within my office the idea is being discussed of a possible amendment to Section 6 of TSCA to prohibit the use, production, sale, importation, or exportation of sodium fluoroacetate (known as 'Compound 1080'). At this point I have not proposed adding this to the bill sponsors, and wanted to see if EPA had any TA and/or history with Compound 1080 that you could share? Thanks. Adam

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Sent: 7/21/2015 3:45:37 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

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Please let me know if you would like a call with FIFRA folks on sodium fluoroacetate. Thanks, Sven

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Sent: 7/20/2015 1:14:59 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

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Sent: 6/16/2015 10:07:31 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA on SNURs
Attachments: SNUR Stats.6.16.15.docx

Michal,

Thank you for the technical assistance request on SNURs. Please see the attached chart that responds to your request. In addition, in the requested time period, the only SNURs where the exemption for articles was lifted include mercury SNURs issued October 5, 2007 and July 21, 2010. There were no SNURs submitted during this time period related to a new use in articles.

Also, EPA doesn't agree that SNURs are a de facto barrier. EPA issues a SNUR because we believe it is important to assess the proposed new use before it takes place. If the notice submitter provides information that supports a determination that the new use is not likely to present a risk, EPA would let it go forward.

Finally, we agree that the terms "affirmative" and "reasonable" could be subject to litigation. That said, we do not believe the bar for EPA to demonstrate that those standards are met is very high. We believe that a finding regarding the potential for exposure would most likely be viewed as an "affirmative" finding so long as it is expressly made. We also believe that the requirement that the potential for exposure be "reasonable" does not add much to what the Administrative Procedure Act would require if "reasonable" did not appear in the provision, since a finding by EPA that there was a potential for exposure would likely need to be reasonable to withstand judicial scrutiny in any event.

This technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, June 15, 2015 4:49 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: TSCA TA - SNURs

Sven

In discussing the new ly added SNUR provision with various parties, we were provided with the pasted statistics below. Could you tell us, for each year listed below, how many SNURs EPA issued (and how many of those were applied to articles)? How many of the SNURs listed below applied to articles? Finally, does EPA concur with the statement that SNURs act as a defacto barrier to engaging in a significant new use (and why or why not?)?

Also, as a general matter, when we talked to Jim he told us that what is in S 697 on this matter is EPA's general current practice, ie that if it intends to do a notification about an article it does assess exposure first. What many have raised concerns with about the S 697 language (also pasted below) is not necessarily a concern about EPA's practice, but of the potential for the EPA's practice to become litigatable. For example, wouldn't the words "affirmative" and "reasonable" be words that could be litigated if an articles manufacturer had an issue with what EPA was doing?

Thanks
Michal

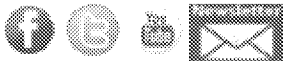
"In theory, SNURs are simply requirements to submit information to EPA before engaging in a significant new use. In practice, SNURs act as a *de facto* barrier to engaging in a significant new use. This may be seen by the paucity of significant new use notices (SNUNs) submitted each year. EPA currently has about 1,685 SNURs, some of which apply to multiple chemicals. Yet almost no SNUNs are filed for those SNURs. See the following:

- FY 2005: 4 SNUNs were filed
- FY 2006: 8 SNUNs were filed
- FY 2007: 6 SNUNs were filed
- FY 2008: 8 SNUNs were filed
- FY 2009: 7 SNUNs were filed
- FY 2010: 2 SNUNs were filed
- FY 2011: 11 SNUNs were filed"

"(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



This information is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Assumptions:

1. As of Last SNUR publication date of June 5, 2015
2. Counted by FR Publication Date
3. Includes Final /Direct Final Rules
4. Includes New and Existing Chemical Substances
5. Counted by 40 CFR Citations
6. Does not count Withdrawn Chemical Substances

	Fiscal Year	Calendar Year
2005	0	1
2006	2	1
2007	85	87
2008	2	45
2009	80	35
2010	56	57
2011	2	34
2012	278	346
2013	147	47
2014	85	102
2015	77	59
Total	814	814

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/17/2015 11:16:34 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
Subject: Sen. Booker TSCA TA Request on Compound 1080

Adam –

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Sent: 6/16/2015 5:16:35 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA on Asbestos

Yes – we're prepared for a call. I'll check on availabilities for later this week. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, June 16, 2015 1:15 PM
To: Kaiser, Sven-Erik
Subject: Asbestos

Possible to do a call on Asbestos definition with myself and the Sand Stone and Gravel folks this week?

Thanks.

jb

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/15/2015 1:19:11 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Senate TSCA TA Request on Nomenclature

Dimitri,

This responds to your technical assistance request on nomenclature language. Please take a look at the TA below and let me know if you would like a call today to discuss. We're open today except 12-1 and 4-5.

Thanks,
Sven

The apparent intent of the new language is for EPA to establish a procedure whereby manufacturers of new "Class 2 substances from new renewable sources" can obtain exemptions from otherwise applicable PMN requirements, if "sufficiently similar" chemical substances are already listed on the TSCA Inventory. The way to achieve this objective without triggering serious implementation concerns is by defining a new basis for exemption from Section 5, and then directing EPA to further elaborate the exemption process by rule.

The current drafting is problematic in two key respects:

- First, because it is structured as a "nomenclature" issue, the language does not specify who is responsible for doing what. For example, what does it mean for one chemical substance to "rely" on another chemical substance? This cannot be construed literally. Is the intended implication that the prospective manufacturer of one chemical substance may unilaterally "rely" on the fact that another chemical substance is listed on the Inventory, and thus conclude that it has no duty to submit a PMN? Or does the prospective manufacturer have a duty to submit an application to EPA and persuade EPA that the two chemical substances are indeed sufficiently similar and that the renewable source in question is sufficiently "new"?
- Second, by framing this provision as a general "nomenclature" issue, it suggests a broader principle: that when EPA adds a chemical substance to the TSCA Inventory, the listing represents not just that one substance but also all "sufficiently similar" chemicals. This is not how EPA currently implements the TSCA Inventory, and redefining the operation of Inventory could have far-reaching and unintended consequences (e.g., when reviewing a new chemical substance, would EPA need to make the "likely to meet the safety standard" finding not only for that one chemical but also for all "sufficiently similar" chemicals?). The general premise of the TSCA Inventory, to date, has been that two different chemical substances require two different entries on the TSCA Inventory, even if they are similar chemical substances. Departing from this basic premise is likely to make the naming and listing process more complex and less transparent.

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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, July 14, 2015 2:54 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: TA Question

Sven,

Quick question for you, any TA we could get back as soon as possible on this would be much appreciated. I think your folks will understand the purpose but it has been proposed to me that we add this language in red below. Want to make sure it would work and not be impossible to implement or objectionable.

Thanks!

((3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled ‘Candidate List of Chemical Substances’, and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); ~~and~~

(iii) establish a process in which Class 2 substances from new renewable sources are evaluated against existing Class 2 substances for equivalence; if an existing Class 2 substance can be found that is sufficiently similar to the new Class 2 substance derived from a renewable source, the new Class 2 substance can rely on the Inventory listing of the existing Class 2 substance; and

(iv) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

(I) cement, Portland, chemicals, CAS No. 65997–15–1;

(II) cement, alumina, chemicals, CAS No. 65997–16–2;

(III) glass, oxide, chemicals, CAS No. 65997–17–3;

(IV) frits, chemicals, CAS No. 6 65997–18–4;

(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402–11 68–4.

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/11/2015 2:45:32 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on workplan chemicals

Michal,

Thank you for the TA request on the description of workplan chemicals. The draft description looks ok to EPA. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Jul 10, 2015, at 7:03 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Think this is an accurate characterization of what workplan chemicals are?

- <!--[if !supportLists]--><!--[endif]-->chemicals it is assessing because they have been identified by EPA as being among the chemicals having the highest potential for exposure and hazard.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

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